

REMARKS

Claims 1-8 are pending. In accordance with the foregoing, claim 1 is amended to correct informalities. Applicant respectfully requests entry and consideration of the foregoing amendments, which are believed to place claims 1-8 in condition for allowance.

The IDS form is indicated as non-compliant. Entry BF of the IDS form submitted 17 September 2004 is submitted herewith.

The U.S.P.T.O. has objected to the drawings. Applicant has corrected Figure 1 in the Replacement Sheet filed herewith and corrected the numbering of line 263 in the specification by the foregoing amendment, thereby obviating the objection.

Claims 1-8 stand rejected under 35 U.S.C. 112, first paragraph as being indefinite. The U.S.P.T.O. indicates that "mapping locations" is not described in the original specification. Applicant respectfully traverses. In paragraph 53, pacing site selection is described as including electrical mapping. In paragraphs 55 and 56, one electrical mapping method is described in more detail. "A zone 220 within interventricular septum 7, as illustrated in Figure 14, was found to be one in which pacing stimulation results in a rhythm breaking out at an intrinsic location, i.e. that of normal sinus rhythm. Rhythm breakout locations were determined...via non-contact mapping. . . ." The process of identifying such rhythm breakout locations via mapping can therefore be referred to as "mapping locations." Paragraph 56 goes on to describe the further optimization of pacing and detection of ventricular activity within zone 220 by positioning electrode(s) to meet specific electrical criteria, and paragraph 57 describes alternative methods for positioning electrodes or selecting from an array of electrodes inserted in zone 220 at various points. Clearly, these various points or positions are locations within the identified interventricular zone that are mapped according to a ratio of measured P-wave amplitude to R-wave amplitude and a pacing threshold measurement as described in paragraph 56 for optimizing detection

and pacing. As such, Applicant respectfully asserts the originally-filed specification provides written description support of "mapping locations" and selecting "mapped locations" and requests withdrawal of the rejection.

Claims 1-8 also stand rejected under 35 U.S.C. 112, second paragraph as being indefinite. The U.S.P.T.O. states it is unclear if the method contains steps for measuring the ratio and for measuring the pacing threshold. Claim 1 has been amended to explicitly recite that the step of mapping locations according to a ratio of measured P-wave amplitude to R-wave amplitude and a pacing threshold measurement "comprises measuring a P-wave amplitude and an R-wave amplitude at each mapped location to determine the ratio and measuring a pacing threshold at each mapped location."

Claims 2-7 stand rejected for having insufficient antecedent basis for "the step of positioning an electrode." Claim 1 has been corrected to provide antecedent basis.

Claims 1-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mathis (U.S. 6,643,546) in view of Anderson (U.S. 4,453,551) and/or additionally cited references. Claim 1 recites "identifying a zone within an interventricular septum of a patient's heart, which is in proximity to the bundle of His where pacing stimulation results in a rhythm breaking out at an intrinsic location; mapping locations within the identified interventricular septal zone according to a ratio of measured P-wave amplitude to R-wave amplitude and a pacing threshold measurement; selecting an electrode implant site from the mapped locations where a mapped location exhibits a ratio of P-wave amplitude to R-wave amplitude that is less than approximately 0.5 and exhibits a pacing threshold is less than or equal to approximately 1.5 volts; and implanting an electrode at the selected implant site to deliver physiological pacing." Mathis teaches a multi-electrode lead and a process for identifying an optimum electrode or electrodes or pattern of electrodes. The Examiner's interpretation that Mathis includes mapping locations according to a ratio of measured P-wave amplitudes and R-wave amplitudes by virtue of merely

sensing an ECG signal cannot stand under any logical supportable analysis. Mathis never teaches measuring an ECG signal amplitude for determining a ratio, never provides a reason to do so, and never uses a ratio of measured P-wave amplitudes and R-wave amplitudes. The passages cited by the Examiner do not correspond to what the Examiner attributes to them. Mathis teaches searching for an optimum electrode based on the propagation of an emitted signal through the heart by measuring elapsed times Delta T for each electrode. As such, Mathis is not concerned with measuring amplitudes of the ECG signal but addresses measurement of elapsed time between a sensed wavefront at an electrode and a prior electrode (col. 14, lines 6-15). While P-waves and R-waves can both be present in an ECG signal, Mathis is not concerned with measuring a P-wave amplitude since the propagation of a wavefront (QRS signal) through the ventricle is measured. Mathis fails to teach or suggest, among other things, mapping locations according to a ratio of P-wave amplitudes and R-wave amplitudes.

The Examiner relies on Anderson for teaching a ratio of measured P-wave amplitudes and R-wave amplitudes less than approximately 0.5. Anderson teaches tests for distinguishing normal sinus rhythm from ventricular fibrillation using an ECG signal. The Examiner's position with regard to Anderson is that Anderson teaches a ratio of P-wave amplitude to R-wave amplitude because the slope which is a ratio of the entire ECG signal includes both the P- and R-waves amplitudes that is less than approximately 0.5. Applicant submits that a slope of the ECG signal is the time derivative of the signal, not a ratio of the P-wave and R-wave amplitudes. As stated in Anderson at col. 5, line 33, the QRS complex is associated with the steepest negative slope of the whole cycle of the heart. Time intervals at which like slopes occur, e.g. within a 20% range, are recorded. A comparison of the time intervals will indicate the presence or absence of a regular QRS complex. As such, Anderson teaches determining a slope as the time derivative of the ECG signal for determining a peak slope for monitoring R-R intervals. The slope content can also be analyzed. Again, the traces are

differentiated (a time derivative) and a histogram is plotted showing a distribution of the slopes. A ratio of P-wave amplitude to R-wave amplitude is never determined nor used in the methods taught by Anderson. To the contrary, Anderson teaches away from measuring a P-wave amplitude since Anderson teaches eliminating the P and T components of the signal by attenuating all frequencies below 3 Hz and above 18 Hz (the frequency range of the QRS complex) using filters (col. 2, lines 49-58). Since Anderson teaches away from P-wave amplitude measurements, Anderson fails to remedy the deficiency of Mathis relating to mapping locations within the identified interventricular septal zone according to a ratio of measured P-wave amplitude to R-wave amplitude and a pacing threshold measurement. For at least this reason, the combination of Mathis and Anderson fails to make claim 1 obvious to one having ordinary skill in the art. Applicant respectfully asserts the rejection is improper and should be withdrawn.

Applicant respectfully asserts that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Respectfully submitted,

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Date

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